



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

October 19, 2004

Ref: 2005-DAL-WL-2

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Lowell J. Ahl, President
Lowlyn Pharmacies, Inc.
dba Red Cross Drug
111 N. Main St.
Blanchard, Oklahoma 73010

Dear Mr. Ahl:

An inspection of your veterinary drug compounding operation, located at the above address, conducted by investigators of the Food and Drug Administration (FDA) from this office between the dates of May 17 and 26, 2004, disclosed significant violations of the Federal Food, Drug, and Cosmetic Act (the Act). The investigators were accompanied by Ms. Cindy Hamilton, Investigator with the Oklahoma State Board of Pharmacy (OSBP).

The inspection confirmed that your firm has compounded and distributed veterinary drugs, including Nitrofurazone, Enrofloxacin HCL, Omeprazole, Gentamycin Sulfate, Chlorpromazine HCL, Flunixin Meglumine, and Diclazuril. These drugs were compounded using bulk active pharmaceutical ingredients (APIs). FDA's policy regarding the compounding of drugs for use in animals is articulated in Compliance Policy Guide, Section 608.400, issued July 2003. As stated in this policy, FDA is greatly concerned about veterinarians and pharmacies that are engaged in manufacturing and distributing unapproved new animal drugs in a manner that is clearly outside the bounds of a traditional pharmacy practice and that violates the Act, such as compounding that is intended to circumvent the drug approval process and provide for the mass marketing of products that have been produced with little or no quality control or manufacturing standards to ensure the purity, potency, and stability of the product. The veterinary drugs you are compounding are unsafe within the meaning of section 512 of the Act (21 U.S.C. § 360b) since they are not the subject of approved New Animal Drug Applications. As such, they are adulterated under section 501(a)(5) of the Act (21 U.S.C. § 351(a)(5)).

Sections 512(a)(4) and (5) of the Act (21 U.S.C. 360b(a)(4) and (5)), and their implementing regulations, allow some extralabel use of approved animal and human drugs, including compounding from such approved animal and human drugs. These provisions, however, apply only to approved drugs and do not permit compounding from bulk APIs (see Title 21, Code of Federal Regulations (CFR), 530.13(a)).

A significant number of your compounded veterinary drugs appear to be compounded outside the context of a valid veterinarian-client-patient relationship (VCPR) for administration by an end user. Instead, they appear to be sales to veterinarians for use as office stock in their professional practice and/or for further distribution. For example, you reported that less than one percent of your product goes directly to the end user, and recent consignee information, provided to investigators for each of the above listed drugs, confirmed that these compounded drugs were shipped to veterinarians. In addition, your records do not identify the animals to receive treatment and your prescription drug labeling does not provide dosage frequency or duration of treatment, further indicating that your firm is compounding these drugs for veterinarians for use as office stock and/or subsequent distribution.

We further note that some of your compounded prescription veterinary drugs are duplicates of FDA approved animal drug products available on the market, and others have only slightly different dosages and/or concentrations than FDA approved animal drugs.

Another concern is that the drugs being compounded could be used in food producing animals and, therefore, could result in unsafe drug residues in edible tissues. This is true even for products labeled "EQUINE USE ONLY" since horses may be offered for slaughter for food. Moreover, at least two of the drugs being compounded, nitrofurazone and diethylstilbestrol, are not permitted for extralabel use in food producing animals because they present a risk to public health.

The above is not intended to be an all-inclusive list of violations by your firm. It is your responsibility to ensure that your firm's operations and products are in compliance with the Act and its implementing regulations. Our inspectional findings were listed on a Form FDA 483, Inspectional Observations, which was issued and discussed with you at the end of the inspection.

You should take prompt action to correct the noted violations and establish procedures whereby they do not recur. Failure to do so may result in additional regulatory action without further notice. These actions include, but are not limited to, seizure and/or injunction.

Within fifteen (15) working days of receiving this letter, you should notify this office in writing of the specific steps you have taken to correct the violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason

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Lowlyn Pharmacies, Inc.
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for the delay and the time period within which the corrections will be completed. You may address your reply to James R. Lahar, Compliance Officer, at the above address.

Sincerely,


Michael A. Chappel
Dallas District Director

MAC:jrl